

## CLO (campylobacter-like organism) test

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## 1. SCOPE AND PURPOSE

To outline the procedure for using the Biohit CLO test for detection of *Helicobacter pylori* infection of the stomach in biopsy samples.

## 2. RESPONSIBILITY

The head of department has overall responsibility for the performance of this assay including adherence to this SOP.

Review and updating of the Standard Operating procedure is the responsibility of the Point of Care Testing Manager.

## 3. REFERENCES

Gut: (1991) vol 32 page 467-469 Thillainayagam et al  
info@biohit.co.uk

## 4. DEFINITIONS

CLO Campylobacter Like Organism

## 5. RELATED DOCUMENTS

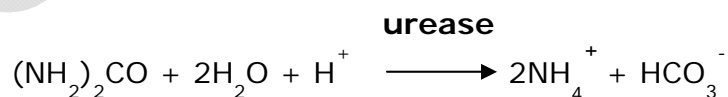
Medical Devices Policy  
Infection Control Policy

## 6. ACTIONS AND METHODS

### 6.1 Principle of test

The Biohit quick test for detecting *Helicobacter pylori* infection in the stomach is based on the activity of the urease enzyme in a biopsy specimen. The biopsy specimen taken from the stomach is examined immediately. The development of the colour in the test gel after 1-2 and 30 minutes indicates whether or not urease enzyme is present in the biopsy specimen.

The assay proceeds according to the following reaction:



*H. pylori* produces a large amount of urease, which degrades urea to ammonia ( $\text{NH}_4^+$ ). The ammonia formed is detected by an indicator colour present in the gel

## **6.2 Personnel to do the task / level of training required**

All qualified members of staff with appropriate training. N.B. The training must be documented

Trainees and unqualified staff, under strict supervision.

## **6.3 Specimen requirements**

Each test plate requires one biopsy specimen, which is recommended to be taken with 5 mm forceps either from the greater curvature of the middle antrum or the corpus. In order to assure high sensitivity, it is recommended that the *Helicobacter pylori* Quick Test is done by using biopsies from antrum and corpus. (*H. pylori* colonization in stomach may sometimes be limited to either antrum or corpus). In performing the gastroscopy, the biopsies for the *Helicobacter pylori* Quick Test should be taken as early as possible to avoid possible errors caused by neutral and alkaline duodenogastric reflux. Before performing the test, blood can be removed from the biopsy specimen by placing it briefly on a sterile gauze pad.

## **6.4 Equipment**

*Helicobacter pylori* Quick Test plate 602015 (50 tests per box).  
Biohit Positive control 602017

## **6.5 Quality Control**

Biohit Urease Positive control solution should be used whenever a new kit is first opened and prior to each clinic.

## **6.6 Method/Procedure**

1. Check that the box of kits has been quality control checked, if they have not a QC must be done before any patient tests are performed.
2. Allow the test plate to reach room temperature for at least 30 minutes before use.
3. Open the label covering the well on the plate and check that the colour of the reagent gel is yellow.
4. If necessary remove blood by briefly placing the biopsy on a piece of gauze then transfer the biopsy specimen from the forceps into the gel of the well, push the biopsy into the gel to ensure it is submersed.
5. Label the test plate to enable unequivocal identification.
6. Incubate for 2 minutes at room temperature (20-25 °C) then check the colour of the gel, if the colour of the gel turns from yellow to red the test is positive if there is no change in colour continue incubation for a full 30 minutes.
7. After 30 minutes check the colour of the gel again, if it has not turned red the test is negative.
8. Record the result in the patient notes and the record book including who performed the test and the batch number and expiry of the test kit.

## **6.7 Sensitivity/specificity**

The technique is reported as having a sensitivity of 94% and a specificity of 88%. The predictive values of a positive and negative test were 89% and 93% respectively

## **6.8 Result Reporting**

Record all results in the patient notes and the record book including who performed the test and the batch number and expiry of the test kit.

Yellow = NEGATIVE (No *Helicobacter pylori* infection indicated)

Red = POSITIVE (Indicative of *Helicobacter pylori* infection)

Any red colour observed in the gel (except blood) should be reported as a positive result.

False positive results

- can occur as a result of contamination by neutral/alkaline substances e.g. due to duodenogastric reflux (the risk of reflux increases if sampling is not performed promptly).
- can occur if tests are read well beyond the 30 minute incubation due to other organisms with low level urease activity.

False negative results

- can occur if *H. pylori* inhibiting antibiotics have been taken <2-4 weeks prior to the examination.
- may occur if acid inhibiting drugs (PPI or H2-blockers) have been taken prior to the examination.

As with any diagnostic procedure the Biohit *Helicobacter pylori* Quick Test results must be interpreted in the light of the patient's clinical presentation and any other information available to the physician.

## **6.9 Guide to interpretation**

*Helicobacter pylori* infection is the most important cause of chronic gastritis. Another mechanism for gastritis and severe atrophic gastritis is the autoimmune mechanism, which can also be triggered by an *H. pylori* infection. The Biohit kit is intended to aid in the diagnosis of *H. pylori* infection in conjunction with upper gastrointestinal endoscopy.

*H. pylori* is a spiral shaped, gram-negative bacterium that colonizes the human stomach. The organism is found in the mucous layer of the stomach overlying the gastric epithelium and it does not appear to invade tissue. However, the mucosa beneath the area of the *H. pylori* colonization is invariably inflamed; this condition is referred to as chronic superficial or non-atrophic gastritis, which, if untreated, persists for life.

The chronic inflammatory process can lead to atrophic gastritis, which has been linked with peptic ulceration and gastric cancer, two of the most important diseases of the upper gastrointestinal tract.

The epidemiological evidence of a link between *H. pylori* infection and gastric adenocarcinoma or mucosa associated lymphoid tissue (MALT) lymphoma has resulted in the classification of the organism as a group I carcinogen.

## **7. HEALTH AND SAFETY/COSHH**

Follow Universal Precautions when handling patient specimens as detailed by the Infection Control Manual. Handle all components and all patient samples as recommended for any potentially infectious human serum or blood specimen in the HHS Publication No. (CDC) 93-8395, Biosafety in Microbiological and Biomedical Laboratories, U.S. Government Printing Office; Washington, DC, 1993, pages 16–18. Use supplied personal protective equipment. Wipe up spills promptly and decontaminate affected surfaces. Avoid generation of aerosols. Follow appropriate waste handling regulations applicable to your area (see Safety Code of Practice section 22).

See COSHH sheets for details of individual reagents:

<http://www.chm.bris.ac.uk/safety/msds.htm>

<http://www.chm.bris.ac.uk/safety/coshh.htm>

<http://physchem.ox.ac.uk/MSDS/>